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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,485	04/21/2006	**Huang-Ping Wu**	BYD02_010_US	5411

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EXAMINER	
SALZMAN, KOURTNEY R	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,485	WU ET AL.	
	Examiner	Art Unit	
	KOURTNEY R. SALZMAN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,13-17,26,30,31,33,45,61,65,68 and 74-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,13-17,26,30,31,33,45,61,65,68 and 74-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Are **DETAILED ACTION**

Response to Amendment

1. The amendment filed on February 1, 2010 has been entered and fully considered.

2. Claims 6, 13, 22, 37 and 38 have been cancelled.

3. Claims 74-85 have been added.

4. Claims 1, 30 and 61 have been amended.

5. Claims 1, 2, 7, 14-17, 26, 30, 31, 33, 45, 61, 65, 68 and 74-85 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 30, 31, 33, 45 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 30 recites the limitation "second redox species" in line 15. There is insufficient antecedent basis for this limitation in the claim. What is assumed to be this species is referred to above in the claim as the "second soluble redox species". Please correct this ambiguity.

b. Claim 45 recites the limitation "the method of claim 37" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no longer a claim 37 as it has been cancelled. Furthermore, in the interest of compact prosecution, the examiner will usually attempt to figure out what the intended

dependency of the claim should be, however, there is no logical group for this claim to be considered with as there is only one method group remaining and it does not disclose the structure of the strip to include a base. Therefore, it is unclear what the applicant intends to do with this claim and this is the sole rejection of this claim.

8. Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

c. Claim 82 is stated to depend on itself, clearly not the intention of the claim. For the purpose of compact prosecution, this claim is interpreted to depend from claim 81 where the third electrode is introduced. Please correct this discrepancy.

9. Claims 61, 65, 68 and 81-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

d. The use of the terms “substrate”, "analyte" and “sample” in the claims listed above, but most noteably in claim 61 is unclear. Claim 61 has been amended to require the quanitifying of the substrate in the sample, however when the definitions supplied by the applicant on page 5, lines 18-29 are consulted, there is no substrate in the sample. Furthermore, the sample is stated to contain the “analyte” whose concentration is to be determined by the sensor, not the concentration of the substrate. In the definition of “analyte”, it is stated that the analyte (which is stated to be present in the sample) can function as a

substrate for the enzyme however, it is indefinite and unclear how something added (the analyte, via its addition in the sample in step one of claim 61) can also function as a support (as the term substrate is known in the art to be) for the enzyme. Utilizing these definitions in light of claim 61, the preamble and the concentrations to be determined are unclear to the examiner. The examiner can agree that the sample (containing the analyte) is added and a redox reaction takes place on a substrate however, it is not understood how this redox reaction finds the “concentration of the substrate” as this is where the reaction is located. Regarding the final limitation, the current which is read from a biosensor is representative of the concentration of the analyte (or substance whose concentration is to be determined). There is no other correlation which is required, while the claim reads as though the current is representative of a substrate concentration which is representative of an analyte concentration. Is it the intent for the concentration of the analyte and substrate be one in the same? Furthermore, the use of two terms, if there intent is for them to be the same, makes the claim confusing. Finally, in light of the definitions in the specification, if the sensor is to be utilized to determine the analyte concentration, it is indefinite how this concentration would be known in the final limitation of the claim requires when comparing it to the substrate concentration. If the sensor is to determine the analyte concentration, as the definition of "analyte" and "sample" teach in the specification, please make this clear.

10. Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

e. Claim 85 seeks a broader range of correlation between the current and concentration than that of the independent claim from with it depends. This is indefinite. Claim 61 seeks patentable protection for a concentration from 0 to 400 mg/dL while claim 85 for a concentration from 0 to 600 mg/dL.

11. Claim 85 recites the limitation "concentration of the analyte" in line 2. There is insufficient antecedent basis for this limitation in the claim.

f. In the amendment to claim 61, the applicant has decided for the concentration of the substrate to be substantially linear from the decided range, not the analyte. Moreover, this entire distinction between substrate and analyte is not clear in reference to the concentration to be determined. This has been rejected also based on indefinitness as well.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 79, 80 and 84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The addition of these claims seek to enter

new matter into the claims. There is no support in the specification for these claims. While the remarks in the third paragraph of page 8 cite claim 32 as originally filed for support, the originally filed claim does not discuss the exclusive presence of these items. There were three sets of claims on record as being filed on April 21, 2006. Two of these sets have no status identifiers (the original filing) and the third has status identifiers indicating this is the amended claims previously examined. In the amended copy of the claims filed April 21, 2006, claim 32 has not only been cancelled but also completely changed in subject matter when compared to one of the first sets of the unamended claims. There is no support for this change, not to mention it isn't properly identified in the status identifier of the claim if the intent was to change the claim or show the claim being amended at all. Furthermore, there is no support for the change to the subject matter of claim 32 between the initial filing and preliminary amendment in the specification. Therefore, this claim cannot be used as a basis for information now, as there was no support at the time of filing any of the amendment sets and there is no support in the specification now.

Claim Rejections - 35 USC § 103

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claims 1, 2, 7, 15, 26, 30, 31 and 74-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA (US 6,287,451), in view of KUHN et al (US 5,385,845) and TANIIKE et al (US PG PUB 2001/0006149).

Regarding claims 1 and 15, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and a mediator (c. 10, l. 49-52), a second electrode (W1 or R) and a second reagent layer comprising a first soluble redox species comprising ferricyanide (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. The new limitation included in the amendment requiring the reagent pieces to be present "prior to use of the sensor strip in an analysis" carries no patentable weight in light of MPEP section 2144 which states that the manner of use of an apparatus does not distinguish it from the prior art. Therefore, as the sample is added, the ferricyanide will react invariably forming ferrocyanide, a second soluble redox species. At some point during processing, it would have been obvious for there to be an excess (or more than 1:1 ratio of the first soluble redox species (ferricyanide) to the second redox species (ferrocyanide, produced during the reaction) because if an excess is not present the reaction with the enzyme cannot proceed, causing an inaccurate reading in the sensor itself. The first redox species would be the limiting agent, causing errors in the sensor concentration readings. In the interest of compact prosecution another interpretation is also presented below giving patentable weight to the final limitation of the claim.

WINARTA et al fails to disclose the use of two mediators placed in the reagent prior to use and explicitly teach the molar ratio of these two redox species.

KUHN et al teaches the application of a reagent layer across two electrodes for the detection of biomaterial comprising the initial presence of both ferrocyanide and ferricyanide (c. 3, l. 30-34). In this citation, KUHN et al teaches the ferricyanide (or first soluble redox species) to be present in a much greater amount than the ferrocyanide (or second soluble redox species). Moreover, KUHN et al teaches benzoquinone species to be used instead of ferricyanide (as in the first reagent mediator) in column 5, lines 63-68.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize the multiple mediators present in one reagent species at the start of processing as in KUHN et al in the second reagent species of WINARTA et al because it is well known in the art to utilize two mediator compounds simultaneously (as taught in paragraph 36 of TANIIKE et al) as the more utilized allows for increased electron transfer capabilities during reactivity. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize benzoquinone in lieu of ferricyanide in the first reagent layer because both are known mediators with the same predictable capabilities of electron transfer and would obviously perform the same predictable result. (TANIIKE et al, paragraph 36, KUHN et al c. 5, l. 63-68).

Regarding claim 2, the composition of the first and second reagent layers is different because, as shown in WINARTA et al, one reagent layer comprises an enzyme while the other does not.

Regarding claims 7, 74 and 75, KUHN et al shows the ferricyanide and ferrocyanide compositions to be present in a ratio greater than 2:1, or about 10:1 in column 3, lines 30-34. Moreover, it would have been obvious to optimize the ratio of the two relative species with undue experimentation to provide the same current limiting effect discussed in KUHN et al.

Regarding claims 26 and 78, a third electrode is shown in to be present in figure 2 as W1 or R (whichever is not utilized as the first electrode). The reagent layer present is described in column 10, lines 41-44. The redox species is ferricyanide, as described in the first and second reagent mixes.

Regarding claim 30, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising glucose oxidase and a mediator (c. 10, l. 49-54), a second electrode (W1 or R) and a second reagent layer comprising a first soluble redox species comprising ferricyanide (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant

application on page 7. The new limitation included in the amendment requiring the reagent pieces to be present "prior to use of the sensor strip in an analysis" carries no patentable weight in light of MPEP section 2144 which states that the manner of use of an apparatus does not distinguish it from the prior art. Therefore, as the sample is added, the ferricyanide will react invariably forming ferrocyanide, a second soluble redox species. At some point during processing, it would have been obvious for there to be an excess (or more than 1:1 ratio of the first soluble redox species (ferricyanide) to the second redox species (ferrocyanide, produced during the reaction) because if an excess is not present the reaction with the enzyme cannot proceed, causing an inaccurate reading in the sensor itself. The first redox species would be the limiting agent, causing errors in the sensor concentration readings. In the interest of compact prosecution another interpretation is also presented below giving patentable weight to the final limitation of the claim.

WINARTA et al fails to disclose the use of two mediators placed in the reagent prior to use and explicitly teach the molar ratio of these two redox species.

KUHN et al teaches the application of a reagent layer across two electrodes for the detection of biomaterial comprising the initial presence of both ferrocyanide and ferricyanide (c. 3, l. 30-34). In this citation, KUHN et al teaches the ferricyanide (or first soluble redox species) to be present in a much greater

amount than the ferrocyanide (or second soluble redox species). Moreover, KUHN et al teaches benzoquinone species to be used instead of ferricyanide (as in the first reagent mediator) in column 5, lines 63-68.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize the multiple mediators present in one reagent species at the start of processing as in KUHN et al in the second reagent species of WINARTA et al because it is well known in the art to utilize two mediator compounds simultaneously (as taught in paragraph 36 of TANIIKE et al) as the more utilized allows for increased electron transfer capabilities during reactivity. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize benzoquinone in lieu of ferricyanide in the first reagent layer because both are known mediators with the same predictable capabilities of electron transfer and would obviously perform the same predictable result. (TANIIKE et al, paragraph 36, KUHN et al c. 5, l. 63-68).

Regarding claim 31, the composition of the first and second reagent layers is different because, as shown in WINARTA et al, one reagent layer comprises an enzyme while the other does not.

Regarding claim 76 and 77, since no specific first soluble redox species is required by the claim, it would be obvious to one of ordinary skill in the art for any

of the materials listed in the specification as possible first soluble redox species, including the ferricyanide of WINARTA et al, to fulfill this requirement. Futhermore, it is known in the art for the reduction potential of ferricyanide is .436 V well above the reduction potentials required by the instnat application.

Regarding claims 79 and 80, WINARTA et al makes it clear the intention of having the enzyme only present in one of the reagent layers and with the combination of KUHN et al, the benzoquinones will only be present on the enzyme electrode. Furthermore, the ferricyanide, with the substitution of benzoquinoes on the first regaent, will only be present in the second, as combined in claims 1 and 30.

16. Claims 61, 65, 68 and 81-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA (US 6,287,451), in view of KUHN et al (US 5,385,845) or TANIIKE et al (US PG PUB 2001/0006149).

Regarding claims 61 and 85, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and a mediator (c. 10, l. 49-52), a second electrode (W1 or R) and a second reagent layer comprising a first soluble redox species comprising ferricyanide (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. WINARTA et al discloses starting a reading by applying a blood sample to the strip in column 13, line 66-column 14, line 1.

WINARTA et al teaches the application of potential, reading the current and correlating to concentrations in column 11, lines 59-66. Moreover, these are standard operating steps for electrochemical gas sensors which obtain readings on concentration. WINARTA et al teaches the final limitation of the claim in example 4 and figure 6 where it is taught that the sensors of WINARTA show a linear realtaionship between current and concentration from 35 to 1000 mg/dL. (c. 14, l. 25-28)

WINARTA et al is not explicit as to the mediator required to be an electroactive organic molecule in the first reagent.

KUHN et al teaches benzoquinone species to be used instead of ferricyanide (as in the first reagent mediator) in column 5, lines 63-68.

At the time of the invention, it would have been obvious to utilize an electroactive organic molecule as in KUHN et al or TANIIKE et al in lieu of the ferricyanide of WINARTA et al because benzoquinones are disclosed to be just as effective subsitutes in performing the electron transfer necessary as ferricyanide, as stated by their interchangeablility taught in KUHN et al and TANIIKE et al (Kuhn et al, c. 5, l. 63-68, TANIIKE et al paragraph 36).

Regarding claims 65 and 68, the first reagent layer comprises glucose oxidase (c. 10, l. 49-54) and the oxidized (or reducible species) mediator ferricyanide (c. 9, l. 15-18) in WINARTA et al.

Regarding claims 81 and 82, a third electrode is shown in to be present in figure 2 as W1 or R (whichever is not utilized as the first electrode). The reagent layer present is described in column 10, lines 41-44. The redox species is ferricyanide, as described in the first and second reagent mixes. The examples 1 and 2 from column 12 to 13 disclose the use of two different potentials for readings of each set of electrodes.

Regarding claim 83, the first and second layers are different due to the inclusion of the enzyme on the first and no enzyme on the second.

Regarding claim 84, WINARTA et al makes it clear the intention of having the enzyme only present in one of the reagent layers and with the combination of KUHN et al or TANIIKE et al, the benzoquinones will only be present on the enzyme electrode. Furthermore, the ferricyanide, with the substitution of benzoquinoes on the first regaent, will only be present in the second, as combined in claim 61.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA et al (US 6,287,451), in view of KUHN et al (US 5,385,846) and TANIIKE et

al (US PG PUB 2001/0006149), as applied to claim 1, in further view of MORRIS et al (Morris, N. A., M. F. Cardosi, B. J. Birch, and A. P. Turner. "An Electrochemical Capillary Fill Device for the Analysis of Glucose Incorporating Glucose oxidase and Ruthenium (III) Hexamine as Mediator." *Electroanalysis* 4.1 (1992): 1-9.).

The combination of WINARTA et al, KUHN et al and TANIIKE et al teaches all the limitations of claim 1, including the use of ferricyanide as the first soluble redox species. The combination of references fails to disclose ruthenium (II) hexamine or ruthenium (III) hexamine as the first soluble redox species.

MORRIS et al teaches a glucose sensor incorporating glucose oxidase with the use of ruthenium (III) hexamine as the mediator of choice in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize the ruthenium (III) hexamine mediator, as in MORRIS et al, as the mediator of WINARTA et al, because the use of a positively charged mediator (ruthenium (III) hexamine) improves the kinetics of the reaction over the use of negatively charged mediator such as ferricyanide, as stated by MORRIS et al on page 7. Moreover, it would have been obvious to substitute one known mediator for another known mediator for the same result of electroactivity and electron-transfer.

18. Claims 16, 17 and 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA et al (US 6,287,451), in view of KUHN et al (US 5,385,846) and

TANIIKE et al (US PG PUB 2001/0006149), as applied to claims 1 and 30, in view of BLOCZYNSKI et al (US 5,520,786).

The combination of WINARTA et al, KUHN et al and TANIIKE et al teach all the limitations of claims 1 and 30, as discussed above including the use of ferricyanide and benzoquinone as the electroactive organic molecule, but fails to detail the use of the materials disclosed in the above stated claims. While glucose oxidase is disclosed in the example, WINARTA et al discloses the use of any enzyme and mediator combination which work together as disclosed in column 8, lines 43-52.

BLOCZYNSKI et al teaches glucose sensor comprising the mediators 3-phenylimino-3H-phenothiazine or 3-phenylimino-3H-phenoxazine in the abstract.

At the time of the invention, it would have been obvious to utilize 3-phenylimino-3H-phenoxazine or 3-phenylimino-3H-phenothiazine, as in BLOCZYNSKI et al, for the ferricyanide mediator of WINARTA et al, because it would have been obvious to substitute one known electron transfer mediator for another. Furthermore, the use of either of the phenothiazine or phenoxazine mediators facilitates electrochemical oxidation at lower potentials than standard mediators, making it more beneficial in regeneration, as stated in column 17, lines 2-17 of BLOCZYNSKI et al.

Response to Arguments

19. Applicant's arguments with respect to all the currently pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

krs
6/2/2010